REMARKS

Applicant's undersigned attorney thanks the Examiner for his comments. Applicant respectfully requests reconsideration of this patent application, particularly in view of the above Amendment and the following remarks.

Applicant's invention is a composition for producing dihydrolipoic acid (DHLA) that acts as a microbiological culture media and produces a harvestable quantity of a naturally-derived dihydrolipoic acid (DHLA) compound. The DHLA is derived from a once-living source, i.e., at least one live DHLA-producing probiotic organism and is suitable for use in a medicament and/or nutritional supplement. The composition includes at least one live DHLA-producing probiotic organism, R-lipoic acid and at least one nutritive agent.

Amendment to the Claims

Claims 4-22 and 24 are pending with Claim 13-19 withdrawn. Claims 4-12, 20-22, and 24 have been examined with no claims allowed.

Claims 4 and 21 have been amended to recite a composition for producing dihydrolipoic acid (DHLA) the composition acting as a microbiological culture media and producing a harvestable quantity of naturally-derived DHLA therein. Support for this amendment is found throughout the specification and, particularly, on page 1, lines 24-26, page 2, line 4-8, page 6, lines 20-25.

Claims 5-10, 12, 13, 16, 18, 20, and 22 have been amended in a manner consistent with the amendments made to Claim 4 and 21.

Claims 5-10, 12, 13, 16-18, 20, and 24 have been further amended to remove the term "stabilized."

Claim 13 has also been amended to recite the steps of dispersing the composition of Claim 4 in water to form a broth and harvesting naturally-derived DHLA from the broth.

Claim 16 has also been amended to recite dispersing the composition of Claim 4 in water to form a broth.

Claim 20 has also been amended to recite that the naturally-derived DHLA produced by the composition is harvested therefrom and used in a medicament or nutritional supplement.

Claim 22 has been amended to depend from Claim 21.

Claim 24 is has been amended to recite a composition consisting of at least one live DHLA-producing probiotic organism, R-lipoic acid, water and tumeric rhizome that acts as a microbiological culture media and produces a harvestable quantity of naturally-derived DHLA therein.

No new matter has been added by this Amendment. Applicant believes that no fees are owed because the number of claims currently pending does not exceed the number originally paid for.

Claim Rejections – 35 USC §112

The rejection of Claims 4-10, 12, 18, and 20-22 under 35 U.S.C. §112, second paragraph as failing to set forth the subject matter which applicant(s) claim as their invention is respectfully traversed.

Although Applicant respectfully submits that a "stabilized" compound such as stabilized DHLA has been adequately defined in the specification and would be clearly understood by a person having ordinary skill in the relevant art as being a compound containing electrons that are aligned and mass accelerated and which thereby emit light (also known as the emission of biophotons), the term "stabilized" has been deleted from the recited claims.

Additionally, Applicant has amended Claim 22 to properly depend from preceding Claim 21.

In view of the above, Applicant respectfully submits that Claims 4-10, 12, 18 and 20-22 properly set forth the subject matter which Applicant claims as his invention. Accordingly, withdrawal and reconsideration of this rejection is respectfully requested.

Claim Rejections – 35 USC §103

The rejection of Claims 4-10 and 20-22 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,368,617 to Hastings et al. in view of Hermann et al (European Journal of Pharmaceutical Sciences, 1996) with additional support provided by Pyruvate Dehydrogenase & Krebs Cycle (1998) and Reed (JBC, 2001) is respectfully traversed.

The core of Applicant's invention is a composition that acts as a microbiological culture media and produces a naturally-derived DHLA compound from a once-living source.

Such naturally-derived DHLA, when consumed as part of a medicament and/or a nutritional supplement and because of the presence of aligned and mass accelerated electrons within the molecular structure of the DHLA molecules which emit photons (also known as biophotons), is believed to be capable of sustaining cellular DNA within the body. The naturally-derived DHLA is produced by feeding a live dihydrolipoic acid-producing probiotic organism R-lipoic acid and at least one nutritive agent such as, for example, tumeric rhizome. The live probiotic organisms in the composition produce a harvestable quantity of a naturally-derived DHLA compound via a metabolic conversion process as the composition is incubated.

In contrast, Hastings discloses a dietary supplement for promoting, upon ingestion, healthy hormone balance in adult human subjects. The dietary supplement include, in addition to a secretagogue known as Symbiotropin in combination with 7-ketodehydrocpiandosterone (7-keto DHEA), alpha-lipoic acid and/or a probiotic blend of *Bifidobacterium bifidum* and *Lactobacillus acidophilus*. Hasting also discloses that an essentially dry powder constituting the dietary supplement can be dissolved in water to provide a daily serving, i.e., a product for immediate or near immediate consumption.

Hermann discloses that R(+)-enantiomer of alpha-lipoic acid has a greater absolute bioavailability than the S(-)-enantiomer of alpha-lipoic acid when consumed by a human.

The Office Action states that it is obvious to use the enantiomerically pure (R) of lipoic acid from the teachings of Hermann to improve the composition of Hastings. It is thus alleged, in view of MPEP §2144.06 that it is prima facie obvious to combine two compositions, the dietary supplement of Hastings and the R-lipoic acid for human consumption of Hermann, to form a third composition to be used for the very same purpose. Logically, the third composition which results from the combination of the teachings of Hastings and Hermann is a dietary supplement for human consumption.

The Office Action further states that Claims 4-10 and 20-22 are drawn to a composition comprising three parts at least one live probiotic organism, R-lipoic acid and at least one nutritive agent. The Office Action further states that any probiotic organism that produces DHLA via its routine metabolic process reads on the claims since Applicant does not define that

DHLA is actually present in the culture media. Additionally, the Office Action states the limitations of microbiological culture media broth are simply a recitation of intended use and therefore given little patentable weight.

Applicant's respectfully submits that Applicant's invention, as recited in presently amended Claims 4 and 21, is a composition that acts as a microbiological culture media and produces a harvestable quantity of a naturally-derived dihydrolipoic acid (DHLA). Thus, in the present instance, Applicant is not combining two compositions each taught as dietary supplements for human consumption, in order to form a third dietary supplement for human consumption. In contrast, Applicant has developed a composition that acts as a microbiological culture medium in which the probiotic organism(s) produce an excess amount of DHLA that can be harvested for use in a dietary supplement for human consumption. In practice, this composition reliably produces a harvestable quantity of naturally-derived DHLA compound outside of the human body that has been used and is being used in a commercially successful product.

Additionally, Hastings in view Hermann does not disclose or suggest that the resulting dietary supplement, a material intended for human consumption, acts as a microbiological culture media that produces a harvestable quantity of dihydrolipoic acid. In contrast, Hastings discloses that alpha-lipoic acid is included in the dietary supplement as an anti-oxidant which coacts with and regenerates several other anti-oxidants to their active states (col. 3, lines 50-55) while probiotic organisms may be included in the dietary supplement to promote intestinal health by increasing and maintaining intestinal flora (col. 5, lines 1-3). Neither Hastings nor Hermann, disclose or suggest that the disclosed dietary supplements produce an excess of naturally-derived DHLA that can be harvested and used for a separate purpose. Further such biological activity is not inherently a characteristic of the compositions of Hastings and/or Hermann given that neither reference suggests or discloses such activity and does not provide any direction as to how to generate a harvestable quantity of naturally-derived DHLA, i.e., how to generate excess DHLA.

The newly cited supporting references, the "Pyruvate Dehydrogenase & Krebs Cycle" article (hereinafter "Reference A") and Reed et al., do not overcome the deficiencies of

Hastings and Hermann. Reference A discloses that lipioc acid can be reduced to dihydrolipoic acid that can in turn be oxidize to lipoic acid as part of the Krebs Cycle. This reference does not disclose or suggest producing excess dihydrolipoic acid but rather demonstrates the cyclic activity of the Krebs Cycle wherein the lipoic acid is conserved; i.e., no new matter is produced.

Reed discloses using lipoic acid and dihydrolipoic acid in substrate amounts to show that extracts of aerobically grown *E. coli* contain lipoyl transacetylase and lipoyl dehydrogenase. Reed does not disclose or suggest that using lipoic acid in connection with a probioitic organism (it is noted that *E. coli* is not generally classified as a probiotic organism) and a nutritive agent produces a harvestable amount of naturally-derived DHLA, that is an excess amount of DHLA for use an entirely separate product.

As Applicant notes on page 1, line 24 – page 2, line 3, lipoic acid and dihydrolipoic acid are naturally synthesized by living organisms at the cellular level. However, cells generally only produce an amount of DHLA sufficient for metabolic function (i.e, for use in the Krebs Cycle). Thus, Reference A and/or Reed add nothing new to this discussion.

Additional or supplemental amounts of DHLA must be derived from external sources. What Applicant has invented is composition which produces naturally-derived DHLA in excess. It is this excess, naturally-derived DHLA, produced by the composition, that can be harvested and used for external supplementation.

For at least the reasons above, Applicant respectfully submits that Hastings in view of Hermann further in view of Reference A and/or Reed does not disclose or suggest a composition including at least one probiotic organism, R-lipoic acid and a nutritive agent acting as a microbiological culture media and producing a harvestable quantity of naturally-derived dihydrolipoic acid therein. Because Claims 5-10 and 20 depend from Claim 4 and Claim 22 depends from Claim 21, these claims are also patentable over Hastings in view of Hermann and further in view of Reference A and Reed. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

The rejection of Claims 11, 12 and 24 under 35 U.S.C. § 103(a) as unpatentable over Hastings in view of Hermann and further in view of U.S. Patent 6,080,401 to Reddy et al. is respectfully traversed.

As discussed above, Hastings in view of Hermann does not disclose or suggest a composition that acts as a microbiological culture media and produces a harvestable quantity of naturally-derived dihydrolipoic acid.

Reddy discloses drugs containing a combination of beneficial micro-organisms, such as probiotic organisms, with drugs of herbal origin, such as *curcuma longa*, for the treatment of a disease or disorder in humans or animals. Reddy, similar to Hastings in view of Hermann, does not disclose or suggest that such combinations can be used as a microbiological culture media broth for producing a stabilized DHLA compound outside of the human body.

For at least the reasons above, Claims 4 and 24 are patentable over Hastings in view of Hermann and further in view of Reddy. Because Claims 11 and 12 depend from Claim 4 these claims are also patentable over Hastings in view of Hermann and further in view of Reddy. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Copy of Claims of Copending U.S. Applications

A copy of the current claims of copending U.S. Patent Application Serial No. 11/028,272 are appended to this Response. It should be noted that these claims remain unchanged since the last Response filed in this application.

Conclusion

If the Examiner feels that any issues remain regarding this application, then Applicant's undersigned attorney would like to discuss the case with the Examiner. The undersigned can be reached at (312) 327-3327.

Respectfully submitted,

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Claims of Co-pending U.S. Patent Application Serial No. 11/028,272

1. (Original) A process for naturally deriving a beneficial compound comprising:

preparing a microbiological culture comprising at least one live probiotic organism and at least one nutritive agent or at least one nutraceutical agent;

incubating the microbiological culture to initiate probiotic activity;

halting the probiotic activity;

harvesting a waste byproduct of the probiotic activity; and

separating the beneficial compound from the waste byproduct.

2. (Original) The process of claim 1 wherein the at least one live probiotic organism is selected from the group consisting of *Lactobacillus* species, *Bifidobacterium* species, *Enterococcus* species, *Streptococcus thermophilus*, and combinations thereof.

3. (Original) The process of claim 1 wherein the microbiological culture is incubated at a temperature of from about 35°C to about 40°C.

4. (Original) The process of claim 1 wherein the microbiological culture is incubated for a period of from about 24 hours to about 240 hours.

5. (Original) The process of claim 1 wherein the probiotic activity is halted by adding organic ethanol.

6. (Withdrawn) The process of claim 1 wherein:

the at least one live probiotic organism is selected from the group consisting of *Lactobacillus* species, *Bifidobacterium* species, *Enterococcus* species, *Streptococcus thermophilus*, and combinations thereof,

the microbiological culture includes at least one nutritive agent and at least one nutraceutical agent which is a source of a B vitamin; and

the beneficial compound comprises at least one B vitamin coenzyme.

7. (Withdrawn) The process of claim 6 wherein the nutritive agent comprises at least one species of nutritional yeast.

8. (Withdrawn) The process of claim 6 wherein the nutritive agent comprises *Saccharomyces cerevisiae*.

9. (Withdrawn) The process of claim 6 wherein the at least one naturally derived B vitamin coenzyme is selected from the group consisting of 5-methyltetrahydofolate, 5-deoxyadenosylcobalamin, pyridoxal-5-phosphate, coenzyme A, inositol hexanicotinamide, riboflavin-5-phosphate, thiamin cocarboxylase, inositol, choline, biotin and combinations thereof.

10. (Withdrawn) The process of claim 6 wherein the microbiological culture is incubated for a period of from about 96 hours to about 240 hours.

11. (Withdrawn) The process of claim 1 wherein:

the at least one live probiotic organism selected from the group consisting of *Lactobacillus* species, *Bifidobacterium* species, *Enterococcus* species, *Streptococcus thermophilus*, and combinations thereof, and

the microbiological culture includes at least one nutraceutical agent.

12. (Withdrawn) The process of claim 11 wherein the naturally derived beneficial compound comprises at least one polyphenol compound.

13. (Withdrawn) The process of claim 12 wherein the nutraceutical agent comprises a material selected from the group consisting of green tea in whole, chopped or powdered form, at least one polyphenol concentrate, and combinations thereof.

14. (Withdrawn) The process of claim 12 wherein the at least one polyphenol compound is selected from the group consisting of epigallocatechin-3-gallate, epigallocatechin, epicatechin-3-gallate, epicatechin, catechin-3-galate, catechin and combinations thereof.

15. (Withdrawn) The process of claim 12 wherein the microbiological culture is incubated for a period of from about 96 hours to about 144 hours.

16. (Withdrawn) The process of claim 11 wherein the naturally derived beneficial compound is UVI-quinol.

17. (Withdrawn) The process of claim 16 wherein the nutraceutical agent comprises UVI-quinone.

18. (Withdrawn) The process of claim 16 wherein the microbiological culture further comprises at least one nutritive agent.

19. (Withdrawn) The process of claim 18 wherein the at least one nutritive agent comprises tumeric rhizome.

20. (Withdrawn) The process of claim 16 wherein microbiological culture is incubated for a period of from about 168 hours to about 196 hours.